

The Department of Vermont Health Access Medical Criteria

Subject: Vibration-Controlled Transient Elastography

Last Review: October 6, 2021*

Past Revisions: January 28, 2020, March 13, 2018, December 29, 2016, and December 30, 2015

***Please note: Most current content changes will be highlighted in yellow.**

Description of Service or Procedure

Vibration-Controlled Transient Elastography is a non-invasive tool that provides assessments of liver stiffness as a surrogate for fibrosis. It measures the velocity of the shear wave generated on the skin. It is used to estimate the degree of liver scarring present. It is very useful in assessment of patients with chronic liver diseases, including chronic hepatitis C (HCV), and chronic hepatitis B (HBV), chronic alcohol abuse, autoimmune disease, and non-alcoholic fatty liver disease. It does not stage fibrosis but rather stratifies risk and correlates very well with fibrosis. The primary benefit of this procedure is the exclusion or inclusion of advanced fibrosis and cirrhosis. In some circumstances, it may reduce the need for an invasive biopsy of the liver. The scan accesses a larger volume of hepatic parenchyma versus a biopsy. It is non-invasive and sedation is not required. It was FDA approved in 2013 and has not been shown to have any side effects. It is simple to use and well-tolerated. The test time is less than 10 minutes. This test allows the physician to make care plans immediately because they do not need to wait for test results as they would with a biopsy.

Disclaimer

Coverage is limited to that outlined in Medicaid Rule or Health Care Administrative Rules that pertains to the beneficiary's aid category. Prior Authorization (PA) is only valid if the beneficiary is eligible for the applicable item or service on the date of service.

Medicaid Rule

Medicaid and Health Care Administrative Rules can be found at <https://humanservices.vermont.gov/rules-policies/health-care-rules/health-care-administrative-rules-hcar/adopted-rules>

- 7102.2 Prior Authorization Determination
- 4.101 Medical Necessity for Covered Services
- 4.104 Medicaid Non-Covered Services



Coverage Position

Transient Elastography may be covered for beneficiaries:

- When the Transient Elastography is prescribed by a licensed medical provider, enrolled in the Vermont Medicaid program, operating within their scope of practice as described on the Vermont's Office of Professional Regulation's website*, who is knowledgeable in the use of Transient Elastography and who provides medical care to the beneficiary AND
- When the clinical criteria below are met.

* Vermont's Office of Professional Regulation's website: <https://sos.vermont.gov/opr/>

Coverage Criteria

Transient Elastography may be covered for beneficiaries who have a diagnosis of HCV, HBV, viral hepatitis, hereditary hemochromatosis, **alcoholic or** non-alcoholic fatty liver disease (NAFLD), when the following criteria are met:

1. A trained operator is performing the test
2. Provider knows the members **alanine aminotransferase** (ALT)
3. Provider knows the member's alkaline phosphatase
4. An XL probe will be used for members with a BMI ≥ 30
5. Member has fasted 3 hours before test
6. Alcohol status of member has been determined
7. Member has been examined for right heart failure
8. Will be performed in conjunction with an assessment of serologic markers of fibrosis

Consideration that may affect test results:

1. Test result accuracy is improved when the provider has experience and completed over 100 exams
2. Increased ALT- inflammation with levels above 100 IU/L
3. Alkaline phosphatase - cholestasis is known to increase stiffness of the liver
4. Congestion from right heart failure may increase liver stiffness
5. Non-fasting
6. Current alcohol status
7. Ascites
8. Large amounts of chest wall fat
9. Morbid obesity (BMI>30)
10. Narrow intercostal margins

Early and Periodic Screening, Diagnostic and Treatment (EPSDT): Vermont Medicaid will provide comprehensive services and furnish all Medicaid coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions for Medicaid members under age 21.

Clinical criteria for repeat service or procedure

Vibration-Controlled Transient Elastography should not be performed more than every six months and is limited to two per year. It should not be performed within 6 months following a liver biopsy.

Type of service or procedure covered

Vibration-Controlled Transient Elastography.

References

- Afdhal, N. (2012). Fibroscan (transient elastography) for the measurement of liver fibrosis. *Gastroenterology & Hepatology*, 8(9), 605-607. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3594956/>
- Centers for Medicare and Medicaid Services. (2021, September). Early and Periodic Screening, Diagnostic, and Treatment. <https://www.medicaid.gov/medicaid/benefits/epsdt/index.html>
- Chang, P.E., Goh, G.B.B., Ngu, J.H., Tan, H.K., & Tan, C.K. (2016). Clinical applications, limitations and future role of transient elastography in the management of liver disease. *World Journal of Gastrointestinal Pharmacology and Therapeutics*, 7(1): 91-106. <https://dx.doi.org/10.4292/wjgpt.v7.i1.91>
- Fang, C., & Sidhu, P.S. (2020). Ultrasound-based liver elastography: Current results and future perspectives. *Abdominal Radiology*, 45, 3463–3472. <https://doi.org/10.1007/s00261-020-02717-x>.
- Ferraioli, G., Wong V.W., Castera L., Berzigotti, A., Sporea, I., Dietrich, C.F., Choi, B.I., Wilson, S.R., Kudo, M., & Barr, R.G. (2018). Liver ultrasound elastography: An update to the world federation for ultrasound in medicine and biology guidelines and recommendations. *Ultrasound in Medicine and Biology*, 44(12) 44, 2419-2440. <https://doi.org/10.1016/j.ultrasmedbio.2018.07.008>
- Hayes, Inc. Health Technology Assessment. Ultrasound Transient Elastography for Detecting Hepatic Fibrosis in Patients with Hepatitis C. Landsdale, PA: Hayes, Inc.; July 2020.
- Kemp, W., & Roberts, S. (2013). FibroScan and transient elastography. *Australian Family Physician*, 42(7), 468-471. <https://www.racgp.org.au/afp/2013/july/fibroscan/>
- Dietrich, C. (2021). Noninvasive assessment of hepatic fibrosis: Ultrasound-based elastography. *UpToDate*. Retrieved September 2, 2021 from https://www.uptodate.com/contents/noninvasive-assessment-of-hepatic-fibrosis-ultrasound-based-elastography/print?search=Vibration-Controlled%20Transient%20Elastography%20&source=search_result&selectedTitle=2~43&usage_type=default&display_rank=2
- Patel, K., & Wilder, J. (2014). Fibroscan. *Clinical Liver Disease*, 4(5), 97 - 100. doi: 10.1002/cld.407
- Tapper, E.B., Castera, L., & Afdal, N. (2015). FibroScan (vibration-controlled transient elastography): Where does it stand in the United States practice? *Journal of Gastroenterology and Hepatology*. 13, 27-36. <http://dx.doi.org/10.1016/j.cgh.2014.04.039>
- Vuppalanchi, R., Siddiqui, M. S., Van Natta, M. L., Hallinan, E., Brandman, D., Kowdley, K., ... Chalasani, N. (2018). Performance characteristics of vibration-controlled transient elastography for evaluation of nonalcoholic fatty liver disease. *Hepatology*, 67(1), 134-144. doi: 10.1002/hep.29489
- Wong, G.L. (2013). Update of liver fibrosis and steatosis with transient elastography (Fibroscan). *Gastroenterology Report*, 1(1) 1926. <https://doi.org/10.1093/gastro/got007>

This document has been classified as public information.